



Subcommittee on Health
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Testimony Before the House Energy and Commerce Subcommittee on Health
on

Legislative Proposals to Promote Electronic Health Records and
A Smarter Health Information System

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Summary

Health Information Exchange (HIE) initiatives are the underpinnings for a system to improve how healthcare is practiced. Recognizing that healthcare is local, the eHealth Initiative and its Foundation are supporting multi-stakeholder HIE collaboration at the state, regional and community levels through the *Connecting Communities* program. Important knowledge related to every aspect of health information exchange is resulting from this work. [see <http://toolkit.ehealthinitiative.org>] The current paradigm of clinical practice limits our ability to avoid errors and control costs. Only with clinical decision support systems (CDSS) integrated into the routine of clinical practice can the system support better healthcare decision making. HIE is a necessary precursor to the operation of CDSS. Requirements for HIE implementation include incentives to stakeholders, assurances regarding privacy and security, and health information system interoperability.

Interoperability is defined with three levels of standards required, from controlled clinical vocabularies, to standardized message structures and entity identification, to a secure communications infrastructure. However, standards are not enough for interoperability. The necessity for inter-institutional exchange of data is forcing a change in the character of standards from the traditional, flexible standards currently in use between systems in the same institution to more complete, rigorous, and tested implementation specifications integrated across standards for specific use cases. Systemic barriers to the rapid deployment of this evolution must be addressed.

This process is likely to take decades before full interoperability of clinical information systems is a reality. There are some low hanging fruit that can be harvested in the near-term, however; medication history, lab results, and interpretive reports, for example. There is an existing suite of standards that addresses these areas of interoperability but most of the standards are not rigorously defined for specific use cases and are inconsistently implemented by vendors. While the HHS AHIC and ONC efforts to kick-start interoperable health information exchange is a good and positive process; it is the start of a very long road. Sustained federal leadership is crucial to achieving these goals and to promoting a smarter healthcare system over time.

Introduction

Chairman Deal, Congressman Brown, distinguished members of the Subcommittee, I am honored to be here today. My name is Bill Braithwaite and I am testifying today on behalf of the eHealth Initiative and its Foundation (eHI). I serve as the Chief Medical Officer of both organizations, which are independent, national, non-profit organizations whose missions are the same: to improve the quality, safety, and efficiency of health and healthcare through information and information technology.

In addition to our main work with communities, we work actively with Congress and the Administration to support these goals and applaud their strong commitment. eHI looks forward to working with you on potential legislation in this area.

The big picture

The field of healthcare is now so vast and complex that practicing medicine with an acceptable error rate is proving to be humanly impossible without the support of integrated information technology. The number of deaths caused by medical errors in our healthcare system every year has been estimated to be 100,000 or higher. I think we would all agree; that is totally unacceptable. And in most cases it is the system that is at fault: we still practice medicine under the old paradigm where the doctor and the patient interact from memory to arrive at healthcare decisions for the patient. The only way to significantly improve the quality, safety, and efficiency of our healthcare system is to bring the information system into the exam room, as it were, and to change the paradigm of clinical practice so that it routinely involves the doctor, the patient, and the computer working together to provide the best healthcare advice possible. The way to implement this new approach is through direct interaction with a Clinical Decision

Support System (CDSS). Such a system must be integrated into the clinical environment in a way that supports rather than disrupts the efficient flow of the process of healthcare. Since most of the data on which clinical decisions are made actually originate outside the exam room, the CDSS by itself is not functional without a way to access the sources of the clinical data, the labs, pharmacies, radiology centers, etc. This, then, is the impetus for eHI's emphasis on interoperable health information exchange initiatives.

Of course, none of these technological innovations will be implemented unless there are sufficient incentives to get these systems incorporated into healthcare practice under a sustainable business model. The needed incentives can take many forms, including pay-for-performance programs that pay providers for higher quality care delivered, and they are discussed in detail in our paper entitled, "Parallel Pathways to Quality Healthcare". In addition, none of the required information sharing will be allowed unless there are sufficient assurances to patients and providers alike that the shared information will be private and secure. In the interest of time, I will leave these two critical prerequisites for others to discuss and refer you to the eHI website for further background material [see <http://www.ehealthinitiative.org/>].

Interoperability

Since most data on which clinical decisions are based come from outside the exam room or other locations where clinical decisions are being made, interoperability for clinical data exchange is a basic and necessary requirement. However, in the healthcare industry there has been some confusion about the meaning of the term, 'interoperability'. The following definitions come from a meta-analysis of over 100 such definitions done by a technical committee of HL7, an international healthcare standards setting organization.

Interoperability is the ability of two or more systems or components to exchange information and to use the information that has been exchanged accurately, securely, and verifiably, when and where needed.

Healthcare interoperability also assures the clear and reliable communication of meaning by providing the correct context and exact meaning of the shared information as approved by designated communities of practice. This adds value by allowing the information to be accurately linked to related information, further developed and applied by computer systems and by care providers for the real-time delivery of optimal patient care.

It is important to understand all the implications of the term, ‘interoperability’, at different levels of abstraction from binary bits of information flowing through a wire at the bottom to the transfer of clinical knowledge at the top. At the highest levels, the context and the exact meaning of information must be preserved and made available for use. In this case, ‘use’ means that the information can be processed by a computer to reach conclusions about what advice to give to a clinician to optimize patient care. That means that the terminology used to describe clinical concepts must be standardized, controlled, and coded in enough detail to differentiate between closely related conditions that might require different treatments, for example. Larger categories of clinical concepts typically used for reimbursement transactions are not sufficiently detailed for this purpose. There are also a large number of clinical concepts which are referred to by different names in different geographic locations. Where locally defined terms are used in lieu of terms from a national standard controlled terminology, then mechanisms must be in place to make the translation to the national standard, a process called ‘normalization’, so that another location that uses its own local terms for a clinical concept can preserve the correct context and

exact meaning. As simple examples that require such standardization, there are 17 different terms that represent the same concept of high blood pressure and there are 27 different potential values for the concept of sex and many different ways to encode them.

At the lowest levels, interoperability implies that there is a standard mechanism that all participants can use to exchange the information securely. Most of us use the world-wide-web every day and understand the power of having such a communications infrastructure available to all. Healthcare, of course, requires such an infrastructure to include more security features than the standard internet connectivity we all use, including authentication, authorization, auditing, encryption, and digital signatures.

In the middle levels are the standards for aggregating discrete data elements together into a meaningful message sent from one system to another in response to an event or 'trigger', standards for identifying the healthcare providers and the patients, and standards for a plethora of other elements that are unique and specific to the use case being implemented.

Clearly, interoperability requires the consistent and rigorous integration of standards of many types and necessarily from many sources. When the only electronic information exchange being considered was that between one system and the next operated by the same institution, it was easy for the technical team(s) to discuss all the specific technical decisions that have to be made before even a well defined standard can be used in a particular business use case. Once the problem is expanded to include the exchange of information among many institutions that may not even be in the same region of the country, the required degree of specificity is sorely lacking

in most of the consensus standards available today and the standards development and maintenance process is perceived to be slow and cumbersome.

It is also critical, with the increasing number of participants in inter-institutional health information exchanges, that the implementations of the standards be tested be conformant to those standards. For example, HL7 standards for transmitting numeric lab results from a laboratory information system to a clinical information system or repository within an institution were some of the earliest implementations of HL7 standards. [Note that HL7 celebrated its 20th anniversary as a standards developing organization in 2006.] However, there are still implementations today where a laboratory (part of a national reference laboratory company) transmits the numeric result of a test in the comment field of a “standard” HL7 message, instead of the result field. This is accommodated in today’s world by writing tailored interfaces for each data flow to bring them to a common implementation of a standard. This is expensive in the short term and untenable in the long term.

The full implementation of standards requires an effective processes for, and ongoing investment in, standards development, support and maintenance, migration, and integration. A range of supporting tools need to be developed and implemented to assist organizations in migrating to standards, including implementation guides, conformance processes, and educational materials. Demonstration and implementation projects are critical to the migration toward an interoperable, electronic healthcare system, in that they test and evaluate feasibility, uncover additional barriers and workable solutions to overcome them, provide replicable practices and tools for others, confirm value for a wide range community stakeholders, and build awareness of the benefits.

The sometimes heard proclamation that, “HIE should wait until the standards are done,” is made by those woefully ignorant of the tasks involved. The many issues discussed above indicate the enormous progress that has been made in the understanding, specification, and adoption of standards. Standards are not static, however, and they must evolve to meet the continuous advances in the delivery of healthcare and can never be ‘done’. To become and remain acceptable, the standards process requires some effort and participation by everyone concerned.

Low hanging fruit

Given that the timeline for full interoperability between clinical information systems is likely to be measured in decades, what can we do in the meantime to reap some of the value of the HIE that we can implement today? If you ask clinicians what the most important information is when they are seeing a patient without a medical record, they quickly iterate medication history, allergies, lab results, problem list, and interpretive reports (e.g., radiology, pathology, and operative reports that are already in electronic form through dictation). The wish list from the patient, however, starts with the data they now have to fill out multiple times on the medical clipboard. Great progress has already been made on many of these and the efforts under the contracts issued by HHS through the Office of the National Coordinator of Health Information Technology (ONC) [see <http://www.hhs.gov/healthit/>] are focusing on these early wins as well as prototypes for the nationwide infrastructure. Results from these funded efforts are expected by the end of this year. In addition, important public-private sector partnerships, such as the Markle Foundation’s Connecting for Health initiative [see <http://www.connectingforhealth.org>], with additional support from the Robert Wood Johnson Foundation, have provided a great deal of

guidance on the technical aspects of health information exchange as well as key principles and policies for information sharing.

Although medication history is not directly involved in most ePrescribing initiatives, it is closely related and likely to evolve quickly based on existing standards as ePrescribing implementations proceed. Laboratory results are being exchanged in some environments today and standards for exchanging most types of results already exist. Full integration with lab test ordering is still being worked on. One approach for interpretive reports that looks promising is the use of a standard electronic message that contains both a human readable representation of the data and a structured and coded form suitable for processing by a computer. Thus, those source systems that are only capable of producing the human readable form (similar to a web page) can still participate in the HIE while those systems with more capability can include data that is fully understood by a computer program. This will allow a migration over time from a simple and easy to produce form of data that is still compatible with the more sophisticated forms in both directions.

It should be absolutely clear from this discussion and these examples, however, that we are still many years away from the fully interoperable health information exchange environment of our vision and there are several intractable barriers to more rapid progress of which we should be aware.

The business case for a vendor to incur the costs of switching to a standard is often muddled at best: short-term narrow objectives are the enemy of long-term, broad interoperability goals.

Even when a vendor understands that implementing standards is good for the product, the resources to do it are not always available. Purchasers have to be informed and insist on standards-based implementations whenever feasible.

Existing standards must be ‘constrained’ (a term of art used by standards setting organizations) into rigorous implementation guides for each particular ‘use case’ (another term of art). A use case is like the outline of a play that defines the goal, the actors, the roles they play, the trigger event(s) that cause them to interact, the data elements that they must exchange, etc. Given a general use case, an implementation guide will allow an implementer to program an information system in a consistent way. It may take several implementation guides based on several standards to implement a particular use case, and the combination of these is often called an ‘integration profile’.

There is a fairly well recognized first set of standards that are already being adopted for HIE. These include: HL7 data interchange standards, the HL7 Reference Information Model, the DICOM standard for imaging, the NCPDP SCRIPT prescription drug information standard, the LOINC vocabulary for laboratory tests, the IEEE/CEN/ISO 1073 medical device communication standard, the ASC X12 administrative transaction standard, HL7 Data Types, HL7 Clinical Document Architecture (CDA), and the HL7 Clinical Context Management Specification (CCOW). Work remains to be done in a number of other domains, including standards related to terminology (and their uniform distribution within the National Library of Medicine’s Unified Medical Language System (UMLS)), clinical templates, clinical guidelines, representation of

business rules, representation of decision support rules, data elements, disease registries, tool sets, security, identifiers, and the electronic health record.

Conclusion

In conclusion, I'd like to thank the Committee for providing me the opportunity to share my insights and expertise on behalf of eHI and its Foundation today. There is a long road ahead but it is filled with the promise of better health for all Americans in their own communities if we work together and get it right on interoperability. Nothing could be more important and eHI will be there to help every step of the way.

APPENDIX A

Health Information Exchange: The eHealth Initiative and Foundation's State, Regional and Community-Based Program Work

Recognizing that healthcare is local—and that to stimulate change in how healthcare is delivered, one must drive change both at the national level and local levels—eHI has been focusing its efforts on supporting multi-stakeholder collaboration at the state, regional and community levels, bringing its common principles, policies and standards developed nationally to those who are delivering healthcare in markets across the U.S. This work is being conducted through the direct funding of learning laboratories at the community level and advocacy and education for additional funding to support local efforts; the building of a coalition or “community” of over 2,000 stakeholders working on health information exchange within over 250 states, regions and communities across the U.S. to share insights and effect change; and the provision of direct technical assistance to leaders within states and regions who are developing strategies and plans to facilitate HIT adoption and health information exchange.

The eHealth Initiative Foundation began its *Connecting Communities* program in FY 2003, through the leadership and foresight of Congressman C.W. Bill Young (R-FL). Though a special appropriation administered by the Department of Health and Human Services' Office of the Secretary, and in years past by the Health Resources and Services Administration's Office of the Advancement for Telehealth (HRSA/OAT), *Connecting Communities* continues to provide seed funding and technical support to a set of “learning laboratories” led by multi-stakeholder collaboratives, who are experimenting with the development of models for sustainability for their

health information exchange efforts. This program will yield valuable lessons learned. Learning laboratories will inform the efforts of policy-makers, and national leaders both in the public and private sectors who must take actions to clear barriers to interoperability and health information mobility.

The 2006 *Connecting Communities* award program will provide learning laboratories for the development and implementation of sustainable business models for health information exchange and build healthcare purchaser and payer awareness of the value that health information exchange capabilities can provide in improving the quality, safety and efficiency of care to stimulate ongoing interest in supporting such activities at the state, regional and local levels. Successful awardees will have engaged the commitment of purchasers and payers representing at least 30 percent of covered lives within their markets, to participate in a pilot or implementation of an incentives program that will not only support quality goals, but also directly or indirectly, support the health information exchange capabilities which are necessary to achieve those quality goals. They will also have engaged the commitment of a large percentage of practicing clinicians--including small physician practices--who have committed to both utilizing the health information exchange capabilities, and participating in the incentives program.

The *Connecting Communities* program is also directly aiding in a task vital to our nation in the wake of Hurricane Katrina: helping to strengthen Gulf Coast healthcare services and regional electronic health information infrastructure in Alabama, Florida, Louisiana, Mississippi, and Texas by supporting public-private sector partnerships as well as assessment, planning,

operational, and communications activities related to the development of health information networks within and across the Gulf States. Prior to Hurricane Katrina, work was being conducted by the Foundation for eHealth Initiative in the Gulf Coast state of Louisiana to assist in general health information technology policy efforts.

The program is also producing informative research and tools valuable to emerging health information exchanges and related policy formation. For example, the *Connecting Communities* Toolkit is a unique, multi-layered, one-stop resource offering structured, how-to synthesis of principles and tools designed to equip states, regions and local communities with the information and expertise to begin or advance local health information exchange initiatives and organizations. It offers insight into areas crucial to start-up and successful survival such as organizational structure, value creation, financing, practice transformation, quality, information-sharing policies, technical aspects and public policy and advocacy. Importantly, it is a distillation of cumulative knowledge resulting from working with multiple stakeholders in different communities. Communities contribute toolkit resources themselves in the spirit of sharing insights with their peers. Its release comes at a critical time as health information exchanges are coming into existence across America and seeking expert advice.

Through eHI's activities on health information exchange, the organization has: become the hub of best practice development and sharing for driving transformation through health information exchange, providing a full range of tools and resources for states, regions and communities who are navigating the organizational, legal, financial, clinical and technical aspects of health information exchange. It is also actively supporting stakeholders engaged in transformation and health information exchange efforts in more than 250 states, regions and communities across the U.S.

In regards to states, the eHealth Initiative has or is in the process of actively supporting 13 states across the country in developing strategies, policies, and plans for improving health and healthcare through health information technology and exchange through its State Policy Summit Initiatives. The goal of these initiatives is to help state public policy officials and key stakeholders in the healthcare and business communities develop state policy agendas and frameworks which support the rapid development and implementation of healthcare information technology and exchange. Some of the states currently being supported by eHI include Arizona, Kansas, Minnesota, New Hampshire, New York, and Ohio.